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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,531	09/05/2003	David Baltimore	CTCH-P01-016	8769

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EXAMINER

PATTERSON, CHARLES L JR

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/656,531

Applicant(s)

BALTIMORE ET AL.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13, 18, 20, 21, 28, 40, 43, 99-104, 106-117 and 119-126 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21, 28, 40, 43, 102-104, 106-117 and 119-126 is/are allowed.
- 6) ☒ Claim(s) 1-11, 13, 18, 20 and 99-101 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

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Prosecution on the merits of this application is reopened on claims are considered unpatentable for the reasons indicated below:

Applicant is advised that the Notice of Allowance mailed 5/3/06 is vacated. If the issue fee has already been paid, applicant may request a refund or request that the fee be credited to a deposit account. However, applicant may wait until the application is either found allowable or held abandoned. If allowed, upon receipt of a new Notice of Allowance, applicant may request that the previously submitted issue fee be applied. If abandoned, applicant may request refund or credit to a specified Deposit Account.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims require that "the DNA binding domain binds to a recognition sequence that occurs at a position in a mammalian genome within 500 base pairs of an allele that is known to contribute to a genetic disorder". The specification does not teach that applicants were in possession of all such binding domains within 500 base pairs of an allele for a genetic disorder and therefore applicants were not in possession of the embodiments of these claims when the application was filed.

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Claims 8 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have not taught one of ordinary skill in the art all sequences that are "within 500 base pairs of an allele that is known to contribute to a genetic disorder" and therefore undue experimentation would be required to practice the instant claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11, 13, 18 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Chandrasegaran (AI). The instant reference teaches a chimeric nuclease comprising three zinc finger domains and the cleavage domain of FokI (column 6, lines 55-63). Column 13, lines 42-45 teaches that "it may be ad-

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vantageous to incorporate a nuclear localization signal (NLS) into the recombinant protein [chimeric restriction enzyme] to ensure that it is expressed within the cell nucleus". Claims drawn to two chimeric nucleases reads on having the same two chimeric nucleases present in the vector.

It is maintained that the requirements of claim 8 and 18 are inherent, absent very convincing proof to the contrary. In the reply filed 8/22/05 applicants argue that Exhibit A, which was attached to the action, "shows the statistics relating to human genetic diversity as of August 16, 2005...[and that] one of ordinary skill in the art can easily use the well-known databases such as OMIM and/or publicly available genome sequence information to identify any gene known to participate in a genetic disease, and design nucleases accordingly". The rejection over claims 8 and 18 were dropped previously because of the inclusion of a NLS in the claims, but the instant reference teaches that. The claim requires that "the DNA binding domain bind to a recognition sequence that occurs...within 500 base pairs of an allele that is known to contribute to a genetic disorder". It is maintained that this requirement is all but impossible for the examiner to determine and that this requirement is inherent, absent very convincing proof to the contrary.

Claims 1-2, 8 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Kelly, et al. (A). The instant reference teaches a fusion protein between the MGMT repair enzyme, the APE enzyme and a nuclear localization signal (Fig. 1B). Fig. 3 shows that the chimeric protein has endonuclease activity. The protein must contain a DNA binding domain since it has endonuclease activity.

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Claims 1, 9 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Giesen, et al. (U). The instant reference teaches a polypeptide comprising a DNA binding domain, a cleavage domain and a nuclear localization signal (abstract and second paragraph of the introduction). The polypeptide is a chimeric protein since Figure 1C teaches the polypeptide fused to a His tag.

Claims 1-11, 13, 18, 20 and 99-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandrasegaran (AI). The use of promoters and viral vectors would have been obvious to one of ordinary skill in the art given the state of the prior art.

Claims 21, 28, 40, 43, 102-104, 1060117 and 119-126 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see

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<http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
August 31, 2006